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PPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/849,781	0	05/04/2001	Michael Snyder	6523-028	9891
20583	7590	12/29/2005		EXAMINER	
JONES DA	λY		TRAN, MY CHAU T		
222 EAST 41ST ST NEW YORK, NY 10017				ART UNIT PAPER NUMBER	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)						
	09/849,781	SNYDER ET AL.						
Office Action Summary	Examiner	Art Unit						
	MY-CHAU T. TRAN	1639						
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address						
Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	1. lety filed the mailing date of this communication. D (35 U.S.C. § 133).						
Status		· · · · · · · · · · · · · · · · · · ·						
1)⊠ Responsive to communication(s) filed on 22 Se	entember 2005	\						
	action is non-final.							
3) Since this application is in condition for allowar		secution as to the merits is						
closed in accordance with the practice under E	·							
olosed in abbordance with the practice and a	x parto quayio, 1000 0.B. 11, 40	0.0.210.						
Disposition of Claims								
4)⊠ Claim(s) <u>See Continuation Sheet</u> is/are pending	g in the application.							
4a) Of the above claim(s) See Continuation She	<u>eet</u> is/are withdrawn from conside	eration.						
5) Claim(s) is/are allowed.								
6) Claim(s) <u>1-11,141,164,166,169,170,173,177,1</u>	☑ Claim(s) 1-11,141,164,166,169,170,173,177,178,181-186,188 and 192 is/are rejected.							
7) Claim(s) is/are objected to.								
8) Claim(s) are subject to restriction and/or	election requirement.							
Application Papers								
9) The specification is objected to by the Examine	r.							
10) The drawing(s) filed on 10 April 2003 is/are: a)	oxtimes accepted or b) $oxtimes$ objected to I	by the Examiner.						
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.						
Priority under 35 U.S.C. § 119								
12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of:		-(d) or (f).						
1. Certified copies of the priority documents								
2. Certified copies of the priority documents	• •							
3. Copies of the certified copies of the prior	·	ed in this National Stage						
application from the International Bureau								
* See the attached detailed Office action for a list of	of the certified copies not receive	d.						
AMarkan and a								
Attachment(s)	A) D Interview Commerce	(DTO 412)						
1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da							
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) D Notice of Informal P	atent Application (PTO-152)						
Paper No(s)/Mail Date	6) Other:							

Continuation of Disposition of Claims: Claims pending in the application are 1-16,93-101,106,107,112-133,138-140,142-159,162,164-167,169-171,173-175,177,178,181-186,188 and 192.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-16,93-101,106,107,112-133,138-140,142-159,162,165,167,171 and 175.

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DETAILED ACTION

Application and Claims Status

- 1. Applicant's amendment and response filed 09/22/2005 is acknowledged and entered. Claims 187 and 189-191 have been cancelled.
- 2. The amendment filed on 11/04/2004: cancelled claims 108-110, 134-136, 160, 161, 163, 168, 172, 176, 179, and 180; amended claims 1, 5, 6, 93, 162, and 164-166; and added claims 181-192.
- 3. The amendment filed on 01/21/2004: amended claims 1-10, 93, 108-109, and 134-135 and added claim 162-180.
- 4. The amendment filed on 08/20/2003: cancelled claims 111, and 137 and added claims 160, and 161.
- 5. The amendment filed on 4/10/03: cancelled claims 17-92, and 102-105.
- 6. Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188, and 192 are pending.

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Election/Restrictions

7. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected the following species for the elected invention (Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-167, 169-171, 173-175, 177, 178, 181-186, 188, and 192) in the reply filed on 08/20/2003:

- a. For the single specific species of the plurality of proteins or molecules, applicant elected the plurality of proteins.
- b. For the single specific species of organism, applicant elected mammal.
- c. For the single specific species of biological activity, applicant elected kinase activity.
- d. For the single specific species of solid support, applicant elected glass slide.
- e. For the single specific species of interaction between the surface of the support and the substance, applicant elected covalently bound.
- f. For the single specific species of assaying reagent. This species is withdrawn in view of applicant argument filed 01/21/2004.
- g. For the single specific species of volumes of the wells, applicant elected the range between 1nl and 1 μ l. However, this election is most with regard to the election of the solid support as being glass slide.
- h. For the single specific species of the bottoms shape of the wells, applicant elected round-shaped. However, this election is most with regard to the election of the solid support as being glass slide.

8. Claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, and 175 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the election requirement filed on 08/20/2003.

9. Claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 are under consideration in this Office Action.

Priority

10. This instant application claims benefit to two provisional applications that are 60/201, 921 filed on 5/4/2000, and 60/221,034 filed on 7/27/2000. This instant application is granted the benefit of priority for 60/201, 921 and 60/221,034 under 35 U.S.C 119(e).

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

- 11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 12. Claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 (*Note: Claims 187 and 189-191 are cancelled*) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claimed invention recites a positionally addressable array. The array comprises a plurality of different substances on a solid support. Each different substance is at a different position on the solid support, and the density of the different substances on the solid support is at least 100 different substances per cm². The plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism selected from the group consisting of a mammal, yeast, and Drosophila.

The specification disclosure does not sufficiently teach the claimed array wherein the kinases are derived from any mammal or any Drosophila. The specification description is directed to a protein comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The description recites a laundry list of the type of organism from which the plurality of different proteins is derived. The specification examples are drawn to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). This array clearly does not provide an adequate representation regarding the claimed array wherein the kinases are derived from any mammal or any Drosophila. Thus the specification does not teach the claimed array wherein the kinases are derived from any mammal or any Drosophila.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u> at page 1116.).

With the exception of a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, disclosed by the specification, the skilled artisan cannot envision the claimed array wherein the kinases is derive from *any* mammal or *any* Drosophila. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for making and using it. See <u>Fiers v. Revel</u>, 25 USPQ2d 1601, 1606 (CAFC 1993) and <u>Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.</u>, 18 USPQ2d 1016. In <u>Fiddes v. Baird</u>, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, <u>University of California v. Eli Lilly and Co.</u>, 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the specification does not teach the claimed array wherein the kinases are derived from *any* mammal or *any* Drosophila. Therefore, only the yeast protein

kinase array, wherein the array comprises 122 different yeast kinases, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

Claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 (Note: Claims 187 and 189-191 are cancelled) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claimed invention recites a positionally addressable array. The array comprises a plurality of different substances on a solid support. Each different substance is at a different position on the solid support, and the density of the different substances on the solid support is at least 100 different substances per cm². The plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism selected from the group consisting of a mammal, yeast, and Drosophila.

The specification disclosure does not sufficiently teach the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "molecules comprising functional domains thereof"), and these analogues are derived from any mammal, any yeast, or any Drosophila. The specification description is directed to a protein comprising a plurality of different proteins on a solid support (see specification: pg. 3, line 33 thru pg. 4, line 2; pg. 10, line 3 thru pg. 11, line 25). The description recites a laundry list of the type of organism from which the plurality of different proteins is derived. The specification examples

are drawn to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). This array clearly does not provide an adequate representation regarding the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "molecules comprising functional domains thereof"), and these analogues are derived from any mammal, any yeast, or any Drosophila. Thus the specification does not teach the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "molecules comprising functional domains thereof"), and these analogues are derived from any mammal, any yeast, or any Drosophila.

<u>Vas-Cath Inc. v. Mahurkar</u>, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u> at page 1116.).

With the exception of a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, disclosed by the specification, the skilled artisan cannot envision the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "molecules comprising functional domains thereof"), and these analogues are derived from any mammal, any yeast, or any Drosophila. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V.

Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

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In the present instance, the specification does not teach the claimed array wherein the plurality of different substances is kinase analogue (refers to the limitation of "molecules comprising functional domains thereof"), and these analogues are derived from any mammal, any yeast, or any Drosophila. Therefore, only the a yeast protein kinase array, wherein the array comprises 122 different yeast kinases, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

Withdrawn Objection(s) and /or Rejection(s)

14. The rejection of claims 1, 187, and 189-191 under 35 USC 112, first paragraph (written description) has been withdrawn in light of applicant's cancellation of claims 187, and 189-191.

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15. The rejection of claims 1, 187, and 189-191 under 35 USC 112, first paragraph (enablement) has been withdrawn in light of applicant's cancellation of claims 187, and 189-191.

16. The rejections of claim 187 under 35 USC 112, second paragraph, as being indefinite has been withdrawn in light of applicant's cancellation of claim 187.

Response to Arguments

17. Applicant's arguments directed to the rejection under 35 U.S.C. 112, first paragraph (written description), for claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 (*Note: Claims 187 and 189-191 are cancelled*) have been fully considered but they are not persuasive for the following reasons.

Applicant alleges that the specification does 'provide written description for the pending claims, in view of the cited case law, and the cited cases are inapplicable to the pending application. First, in each of the cases the Office Action cites, the claims at issue were directed towards novel DNA or protein molecules themselves, rather than methods or compositions involving proteins. Second, in each of the cited cases, the claims were directed to novel DNA or protein molecules, where the identity of the molecule was unknown prior to the filing date of the patents at issue'. Thus, the instant specification does 'provide written description for the pending claims'.

Applicant's arguments are not convincing since the instant the specification fails to 'provide written description for the pending claims'.

First although the cited case laws directed to DNA compounds, these cases laws would be deemed to be applicable to any compound or a generic/genus of compounds, which requires a representative sample of compounds and/or a showing of sufficient identifying characteristics to demonstrate possession of the compound or generics/genus. Especially, Eli Lilly holding sets forth a two part test for written description: A description of a genus of cDNA's may be achieved by means of a recitation of: a representative number of cDNA's, defined by nucleotide sequence, falling within the scope of the genus **OR** of a recitation of structural features common to the members of the genus. See Regents of the University of California v. Eli Lilly & Co. 119 F.3d 1559 (Fed. Cir. 1997) at 1569. In this case, the pending claims are directed to the genus of protein kinase of the genus of eukaryotes and prokaryotes, i.e. the organism of mammal, yeast, and Drosophila. Yet, the instant specification disclosure is directed to the yeast protein kinase, specifically 122 different yeast protein kinases (see specification: example I, pg. 27, line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). Furthermore, the specification discloses that "the yeast genome has been sequenced and contains approximately 6200 open reading frames greater than 100 codons in length; 122 of these are predicted to encode protein kinases" (i.e. there is a possible 122 protein kinases found in a yeast genome) (pg. 27, lines 32-34). However, this is not the definitive total number of protein kinases in a yeast genome since it is a *predicted* number. In fact, Hunter et al. (TIBS, 1992, 22(1), pgs. 18-22) disclose that there is no consensus in the total number of protein kinase of a yeast genome wherein they found a total of ~120 protein kinases, which is less than the estimate number of yeast protein kinases that was based on the sequencing of chromosome III (pg. 21, 2nd col., line 62 to 3rd col., line 5). Since there is no definitive total number of protein kinase for a yeast genome, i.e. the genus of protein

kinases within a single species of yeast, the specification clearly does not provide an adequate representation regarding the genus of protein kinase of the genus of eukaryotes and prokaryotes, i.e. the organism of mammal, yeast, and Drosophila. Furthermore, the prior arts discloses that the 'entire' genus of protein kinase superfamily have yet to be discover since the entire genomic sequencing of the genus of eukaryotes and prokaryotes have yet to be completed (see Hanks et al. cited by applicant; *FASEB*, **1995**, 9(8), pgs. 576-596; pg. 595, right col., lines 19-60).

Second, it is the examiner position that the pending claims are 'directed towards novel DNA or proteins' as claimed in claim 1. Claim 1 recited the limitation of 'the plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism'. The limitation of 'or molecules comprising functional domains thereof' encompasses known and unknown, i.e. novel, DNA and proteins.

Therefore, the instant the specification fails to 'provide written description for the pending claims', and the rejection is maintained.

18. Applicant's arguments directed to the rejection under 35 U.S.C. 112, first paragraph (written description), for claims 1-11, 141, 164, 166, 169, 170, 173, 177, 178, 181-186, 188, and 192 (*Note: Claims 187 and 189-191 are cancelled*) have been fully considered but they are not persuasive for the following reasons.

Applicant contends that the specification does 'provide written description for the pending claims, in view of the cited case law, and the cited cases are inapplicable to the pending application. First, in each of the cases the Office Action cites, the claims at issue were directed towards novel DNA or protein molecules themselves, rather than methods or compositions

involving proteins. Second, in each of the cited cases, the claims were directed to novel DNA or protein molecules, where the identity of the molecule was unknown prior to the filing date of the patents at issue'. Thus, the instant specification does 'provide written description for the pending claims'.

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34). However, this is not the *definitive* total number of protein kinases in a yeast genome since it is a *predicted* number. In fact, Hunter et al. (*TIBS*, 1992, 22(1), pgs. 18-22) disclose that there is no consensus in the total number of protein kinase of a yeast genome wherein they found a total of ~120 protein kinases, which is less than the estimate number of yeast protein kinases that was based on the sequencing of chromosome III (pg. 21, 2nd col., line 62 to 3rd col., line 5). Since there is no definitive total number of protein kinase for a yeast genome, i.e. the genus of protein kinases within a single species of yeast, the specification clearly does not provide an adequate representation regarding the genus of protein kinase of the genus of eukaryotes and prokaryotes, i.e. the organism of mammal, yeast, and Drosophila. Furthermore, the prior arts discloses that the 'entire' genus of protein kinase superfamily have yet to be discover since the entire genomic sequencing of the genus of eukaryotes and prokaryotes have yet to be completed (see Hanks et al. cited by applicant; *FASEB*, 1995, 9(8), pgs. 576-596; pg. 595, right col., lines 19-60).

Second, it is the examiner position that the pending claims are 'directed towards novel DNA or proteins' as claimed in claim 1. Claim 1 recited the limitation of 'the plurality of different substances consists of at least 61 kinases or molecules comprising functional domains thereof of an organism'. The limitation of 'or molecules comprising functional domains thereof' encompasses known and unknown, i.e. novel, DNA and proteins.

Therefore, the instant the specification fails to 'provide written description for the pending claims', and the rejection is maintained.

Conclusion

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19. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct December 20, 2005

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